SEP 18

NDA 8-857/S-009

Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, PA 19 10 l-8299

Attention: Nanette E. Holston
Manager
U.S. Regulatory Affairs

Dear Ms. Holston:

Please refer to your supplemental new drug application dated September 2 1, 198 1, received September 21, 198 1, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Phenergan (promethazine hydrochloride) Injection, 25 and 50 mg/mL.

We acknowledge receipt of your submissions dated May 3,1988, February 1, March 1, and May 15,1989, January 7,1992, August 6,1996, and May 8 and August 21,1998. Your submission of May 8, 1998, constituted a full response to our February 21, 1997, action letter.

This supplemental new drug application provides for revised labeling.

We have completed the review of this supplemental application, including the draft package insert dated May 8, 1998, and the final printed carton and container labels dated August 21, 1998, and it is approved effective on the date of this letter.

The final printed labeling (FPL) for the package insert must be identical to the draft package insert submitted May 8,1998.

Please submit 20 copies of the FPL for the package insert as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement 8-857/S-009." Approval of this submission by FDA is not required before the labeling is used.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of the labeling may be required.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Mr. David Hilfiker, Project Manager, at (301) 827- 1046.

Sincerely yours,

JohnK. Jenkins, M.D., F.C.C.P.
Director
Division of Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Phenergan
(promethazine HCl)
Injection
25 mg per mL

1 03 0008 0416 01 0

2924P M BL-L BL
2924P

NDC 0008-0416-01

Phenergan®
(promethazine HCl)
Injection

25 mg per mL

Ten—1 mL size
22 gauge
1¼ inch needle

Caution: Federal law prohibits dispensing without prescription.

Wyeth Laboratories Inc.
A Wyeth-Ayerst Company

25 mg per mL
22 gauge
1¼ inch needle

Phenergan
(promethazine HCl)
Injection

EXP

LOT

Phenergan
(promethazine HCl)
Injection
50 mg per mL

1 03 0008 0417 01 7

2924P M BL-L BL
2924P

NDC 0008-0417-01

Phenergan®
(promethazine HCl)
Injection

50 mg per mL

Ten—1 mL size
22 gauge
1¼ inch needle

Caution: Federal law prohibits dispensing without prescription.

Wyeth Laboratories Inc.
A Wyeth-Ayerst Company

50 mg per mL
22 gauge
1¼ inch needle

Phenergan
(promethazine HCl)
Injection

EXP

LOT

LOT DH 9-14-98
EXP.

25 Ampuls—Each contains **1 mL**
NDC 0008-0063-01 6505-00-680-7352

NDC 0008-0063-01-9

Phenergan® Injection
(Promethazine HCl Injection, USP)

25 mg/mL

FOR DEEP INTRAMUSCULAR OR INTRAVENOUS USE

Each mL contains promethazine hydrochloride 25 mg, edetate disodium 0.1 mg, calcium chloride 0.04 mg, sodium metabisulfite 0.25 mg and phenol 5 mg in Water for Injection. pH 4.0-5.5; buffered with acetic acid-sodium acetate. Sealed under nitrogen.

USUAL DOSAGE: See package insert for complete prescribing information. **PROTECT FROM LIGHT**: Keep covered in carton until time of use. Store at controlled room temperature 15°-30° C (59°-86° F).

DO NOT USE IF SOLUTION HAS DEVELOPED COLOR OR CONTAINS A PRECIPITATE.

To open ampuls, ignore color line; break at constriction.

Caution: Federal law prohibits dispensing without prescription.

Wyeth Laboratories Inc.
A Wyeth-Ayerst Company
Philadelphia, PA 19101

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